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| 10/596,158      | 09/29/2006  | Hans Jorg Meisel     | 17346-0033          | 2935             |

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SUTHERLAND ASBILL & BRENNAN LLP  
999 PEACHTREE STREET, N.E.  
ATLANTA, GA 30309

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| EXAMINER |
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SCHNEIDER, LYNN SY M

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| ART UNIT | PAPER NUMBER |
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3733

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01/31/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/596,158             | MEISEL, HANS JORG   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | LYNNSY SCHNEIDER       | 3733                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-14,16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-14,16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9-14, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishijima et al. (Pat. No. US 5,899,941) in view of Ogle et al. (Pat. No. US 6,322,588 B1).

3. Regarding claims 1-7, 9, and 10, Nishijima et al. discloses a parts assembly 2, 3 (figure 1A) for a prosthesis 1, particularly a cervical spine intervertebral disc prosthesis, comprising two base parts 2, 3, which are coupled to one another in an articulated manner by means of coupling parts 11, 15 (figure 1B) formed on the base parts 2, 3, wherein the base parts 2, 3 are in each case formed in one piece with an associated coupling part 11, 15, wherein the base parts 2, 3 and their associated coupling parts 11, 15 are made of the same material (col. 5, lines 20-30), wherein one of the coupling parts 11 comprises a sliding surface "arc shape" and the other of the coupling parts 3 comprises a countersliding surface 15. An anatomically adapted contact surface 6, 7 (figure 3A) is formed on a respective outer side of the two base parts 2, 3 (figure 3A). An anti-rotation means 20, 20a (figures 1A, 2) is formed on each of the two base parts 2, 3. The anti-rotation means 20, 20a comprises a web arranged on the respective outer side (col. 3, lines 30-33). The two base parts 2, 3 are coupled to one another in

Art Unit: 3733

an articulated manner by means of a sliding connection (figures 4-6B). The sliding connection is embodied by means of the sliding surface “arc shape” and the countersliding surface 15, which is adapted to the sliding surface “arc shape”, wherein the sliding surface is slidably supported on the countersliding surface in the coupled state of the two base parts 2, 3 (figure 1A). The sliding surface is formed on a hemispherical protrusion 11 on the coupling part 11 (figure 1A; col. 2, lines 64-67). The two base parts are at least partially coated (in the region of the webs, there is a hydroxyapatite coating). The webs have a material coating (col. 5, lines 33-36).

Regarding claims 11-14, 16, 18, and 19, Nishijima et al. discloses a part for a prosthesis parts assembly (figure 1A), particularly a cervical spine intervertebral disc prosthesis part, comprising a base part 2 and a coupling part 11 formed on the base part 2 for articulated coupling to another base part 3 (figure 1A), wherein the base part 2 and the coupling part 11 are formed in one piece, and made of the same material (col. 5, lines 20-30), wherein the coupling part 11 comprises a sliding surface “arc shape”. An anatomically adapted contact surface 6 on an outer side of the base part 2 is provided (figure 3A). An anti-rotation means 20, 20a on the outer side of the base part 2 is provided (figures 1A, 2). The anti-rotation means 20, 20a comprises a web arranged on the respective outer side (col. 3, lines 30-33). The sliding surface “arc shape” is curved. The base part 2 is at least partially coated (in the region of the webs, there is a hydroxyapatite coating). The webs have a material coating (col. 5, lines 33-36).

Nishijima et al. does not disclose wherein the material is a material selected from the following group of materials: polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK), and wherein the sliding surface and countersliding surface are coated in a coating material based on a chromium-nickel alloy.

However, Ogle et al. teaches that it is advantageous to form orthopedic spinal implants (col. 3, line 45; col. 4, line 3) of a polymer with a metal coating, wherein the polymer can be chosen from a group containing the material Polyether ether ketone (col. 5, lines 10-12), and wherein the coating is a material based on a nickel-chromium alloy (the material is a cobalt-nickel-chromium alloy, col. 4, lines 13-23), the polymer/metal composite being advantageous because the strength of the metal can be combined with the versatility of the polymer, thereby combining the advantages of both metals and polymers in a synergistic fashion to arrive at improved implantable components. The polymer may provide the desired structural features and the metal may coat all or part of the polymer in order to improve the strength of the implant (col. 2, lines 20-67).

It would have been obvious to one skilled in the art at the time the invention was made to form the base parts and coupling parts of the device disclosed by Nishijima et al. of a polymer material, in particular a polymer chosen from a group including PEEK, and to coat the spinal implant of the Nishijima et al. reference with a cobalt-nickel-

Art Unit: 3733

chromium alloy as taught by Ogle et al. for the purpose of combining the strength of the metal with the versatility of the polymer, thereby combining the advantages of both metals and polymers in a synergistic fashion to arrive at improved implantable components. The polymer may provide the desired structural features and the metal may coat all or part of the polymer in order to improve the strength of the implant (col. 2, lines 20-67).

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1-6, 8-14, 16, 18, and 19 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's argument that a person of skill in the art would not have known that the abrasion resistance of sliding and countersliding surfaces could be increased by applying a coating material based on chromium-nickel alloy, it is noted that the claim language only requires the surfaces to be coated in a coating material based on a chromium-nickel alloy. Olge et al. teaches that an orthopedic spinal implant can be formed of a polymer (PEEK) coated in a cobalt-chromium-nickel alloy, which satisfies the claim limitations. The fact that the cobalt-chromium-nickel alloy of Olge et al. is disclosed as having advantages which are different than providing increased abrasion resistance does not matter. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Furthermore, the fact that Applicant uses the coating for a different purpose does not alter the conclusion that its

Art Unit: 3733

use in a prior art device would be prima facie obvious from the purpose disclosed in the reference.

In response to Applicant's argument that Olge et al. does not disclose a chromium-nickel alloy, it is noted that the claim language requires "a coating material based on a chromium-nickel alloy". Olge et al. discloses a cobalt-chromium-nickel alloy. Examiner takes the position that a cobalt-chromium-nickel alloy is based on a chromium-nickel alloy.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO form 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733